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EXAMINER	
SMITH, CAROLYN L	

ART UNIT	PAPER NUMBER
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/507,389	AOKI ET AL.	
	Examiner	Art Unit	
	Carolyn L. Smith	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *6,7,10-20 and 24-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,8,9 and 21-23* is/are rejected.

7)☒ Claim(s) *8 and 23* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 September 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01132005,08152007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' election without traverse of Group I (claims 1-23), specie C (sensitivity data that comprise clinical sensitivity data for a biological specimen) and second specie (4-[hydroxy-(3-methyl-3H-imidazole-4-yl)-(5-nitro-7-phenyl-benzofuran-2-yl)-methyl]benzonitrile hydrochloride), filed 11/27/07, are acknowledged. Claims 24-31 are withdrawn from consideration as being drawn to non-elected Groups. Claims 6-7 and 10-20 are withdrawn from consideration as being drawn to non-elected species.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The present title is directed to a method for selecting drug sensitivity-determining factors and method for predicting drug sensitivity using the selected factors, whereas in contrast the elected claims are specifically directed to a method for constructing a model that predicts sensitivity to a drug based on expression levels of genes.

The information disclosure statements (IDSs) submitted on 1/13/05 and 8/15/07 were in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the Examiner.

Drawings, filed 9/10/04, are accepted by the Examiner.

Claims herein under examination are 1-5, 8-9, and 21-23.

Claim Objections

Claims 8 and 23 are objected to because of the following informalities: These claims recite "data" in the plural form followed by "comprises" in the singular form. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-5, 8-9, and 21-23 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Under the Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility (published in the O.G. notice (1300 OG 142) on 11/22/2005) a method that does not result in a physical transformation of matter MAY be statutory where it recites a concrete, tangible and useful result; i.e. a practical application.

Claims 1-5, 8-9, and 21-23 are drawn to a method for constructing a model that predicts sensitivity to a drug based on the expression levels of genes. A statutory process must include a step of a physical transformation, or produce a useful, concrete, and tangible result (State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998), AT&T Corp. v. Excel Communications Inc. (CAFC 50 USPQ2d 1447 (1999)). In the instant claims, there is no step of physical transformation, thus the Examiner must determine if the instant claims include a useful, concrete, and tangible result.

In determining if the claimed subject matter produces a useful, concrete, and tangible result, the Examiner must determine each standard individually. For a claim to be "useful," the claim must produce a result that is specific and substantial. For a claim to be "concrete," the process must have a result that is reproducible. For a claim to be "tangible," the process must produce a real world result. Furthermore, the claim must be limited only to statutory embodiments.

In the instant case, claims 1-5, 8-9, and 21-23 do not produce a tangible result. A tangible result requires that the claim must set forth a practical application to produce a real-world result. The method as claimed may take place entirely within the confines of a computer or human mind without any communication to the outside world. Because no practical result is recited in the claims, these instant claims do not include any tangible result. This rejection could be overcome by amendment of the claims to recite that a result of the method is outputted to a display or a memory, or by including a physical transformation (provided there is adequate written support in the originally filed application).

Claims Rejected Under 35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 8-9, and 21-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Claim 1 recites the limitation "using" which is vague and indefinite. It is unclear what step or steps are encompassed by this limitation. Clarification of this issue via clearer claim wording is requested. Claims 2-5, 8-9, and 21-23 are also rejected due to their dependency from claim 1.

Claims 1 (penultimate line), 2 (lines 1-2), 3 (lines 1-2), and 5 (lines 1-2) recite "can predict", "is optimized", and "is constructed" which is vague and indefinite. These limitations are passive steps, making it unclear what active method step is intended to be represented by the limitations. Clarification of this issue via clearer claim wording is requested. Claims 4, 8-9, and 21-23 are also rejected due to their dependency from claim 1.

Claim 2 is vague and indefinite due to the unclarity of citing an abbreviation, such as Q^2. Correction is suggested by amending in of the full name in parentheses. Claims 3-5 are also rejected due to their direct or indirect dependency from claim 2.

Claims 2 (line 4) and 3 (line 3) recite the limitations "small", "high", and "greater relative parameter" which are vague and indefinite. It is unclear what are the metes and bounds of these terms. Clarification of this issue via clearer claim wording is requested. Claim 5 is also rejected due to its dependency from claim 2.

Claim 2 (line 4) recites "and/or" which is vague and indefinite. It is unclear if Applicant intends this limitation to mean "and" or "or". Clarification of this issue via clearer claim

wording is requested. Claims 3-5 are also rejected due to their direct or indirect dependency from claim 2.

Claims 3 and 4 recite the limitation "degree of contribution" which is vague and indefinite. It is unclear to what the contribution is contributing. Is it a contribution to sensitivity, gene expression, a model, or some other scenario? Clarification of this issue via clearer claim wording is requested.

Claim 3 recites the limitation "the genes" twice in lines 2-3. There is insufficient antecedent basis for this limitation in the claim. It is unclear if "the genes" is referring to the genes in claims 1 (line 2), 2 (line 2), or 2 (line 3). Clarification of this issue via clearer claim wording is requested. Claim 4 is also rejected due to its dependency from claim 3.

Claim Rejections – 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 5, 8, 21, and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Rocke et al. (US 2002/0111742 A1).

Rocke et al. disclose a method for generating a model for predicting the classification of a biological sample using partial least squares (PLS)(0009, 0015, 0017) and using gene expression data to predict patient survival, drug sensitivity of a tumor, or other clinical outcomes (0146), as stated in the preamble of instant claim 1. Rocke et al. disclose obtaining data from a biological sample including gene expression measurements and ratios between a reference and test measurement, constructing PLS components to maximize covariance between response values that identify a G group (i.e. different reactions to drug therapy, predicted survival times; claims 17 and 19) (sensitivity data) and the combination of the predictor (gene expression) values such that a prediction can be made in classifying the sample (0032, 0048, claims 1, 3, 13, 14, 16, 17, and 19) (as stated in instant claim 1) and wherein survival times represent clinical sensitivity data (as stated in instant claim 8). Rocke et al. disclose generating different combinations of genes based on a genetic algorithm (0098) and optimizing by extracting K gene components where K<<N (observations) using PLS (0026, 0039, 0054) which represents selecting models in which the number of genes is small, as stated in instant claims 2 and 5. Rocke et al. disclose high density nucleic acid array data that correlate sensitivity of a cell to a drug (0005, 0111, 0146) and analysis procedures for the prediction of biological samples, such as human tumor samples, based on high dimensional data obtained from microarray gene expression measurements (0005, 0016, 0055), as stated in instant claims 21 and 23.

Thus, Rocke et al. anticipate the limitations of instant claims 1, 2, 5, 8, 21 and 23.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. (e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 8, and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rocke et al. (US 2002/0111742 A1) in view of Kovesdi et al. (US 2004/0199334 A1).

Rocke et al. describe the limitations of claims 1, 2, 5, 8, 21 and 23, as stated in the 35 USC 102 rejection above. Rocke et al. do not describe selecting models whose Q^2 value is high (instant claim 2), computing a parameter representing degree of contribution and selecting the greater relative parameter (instant claim 3), a modeling power value (instant claim 4), and an antitumor effect (instant claim 22).

Kovesdi et al. describe a method for providing a model for generating a quantitative structure property activity relationship (QS(P)AR) (abstract) and the prediction of biological

activity and physico-chemical properties of compounds (0001, 0126). Kovesdi et al. describe establishing biological/physical/chemical data providing a model involving partial least squares, selecting significant descriptors according to their influence to the property activity relationship, and verifying the model by use of a quality parameter (claims 1, 7). Kovesdi et al. describe the QS(P)AR can be performed by applying partial least squares (PLS) algorithm to achieve an optimal quality parameter (0051), and model fitting with Q^2 value (square of the predictive correlation coefficient) of model predictions of 0.4 or higher for use as a reliable prediction of biological activity and properties (0070, 0048-0049, 0054, 0056, 0118-0123, 0126-0127), as stated in instant claim 2. Kovesdi et al. describe calculating the absolute values of the descriptors coefficients (parameter) to quickly quantify the importance of the descriptors in the model and selecting the descriptors that have the greater relative parameter (0125-0127) as well as optimal relationships from maximum validated prediction power and achieving an optimal quality parameter (0051, 0132) which represents computing a parameter that represents degree of contribution and selecting those with a greater relative parameter (as stated in instant claim 3) and modeling power value (as stated in instant claim 4). Kovesdi et al. describe analysis of tumor dihydrofolate reductase inhibitors (Example 1) which represents an antitumor effect, as stated in instant claim 22.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to fit a Q^2 value (square of the predictive correlation coefficient) as taught by Kovesdi et al. into the drug predictive model method of Rocke et al. wherein the motivation would have been to correlate large volumes of data to a biological response and extract meaningful information from data such as predicting the biological state of a sample which in turn would

improve the ability to apply genomics data to improve medical diagnoses and treatments, as taught by Rocke et al. (0005).

Thus, Rocke et al., in view of Kovesdi et al., make obvious claims 1-5, 8, and 21-23.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on (571) 272-0720.

February 12, 2008

/Carolyn Smith/
Primary Examiner
AU 1631